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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/653,879 | 09/02/2003 | Timothy B. Petrick | 891,144-001 | 5033 |

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| EXAMINER | |
|---|---|
| CAMPBELL, VICTORIA P | |
| **ART UNIT** | **PAPER NUMBER** |
| 4123 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/653,879 | PETRICK ET AL. | |
| | Examiner | Art Unit | |
| | Victoria P. Campbell | 4123 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,23,31,40,48,57 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14,23,31,40,48,57 and 63* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 23, 40, and 57, drawn to a catheter, classified in class 604, subclass 523.

II. Claims 14, 31, 48, and 63, drawn to a method of catheterization of an artery, classified in class 604, subclass 523.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the inventions of invention I can be used to catheterize other ducts within the body, including the urethra.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species:

**Species A:** The species describing a catheter comprising an elongate tubular member having a proximal end and a distal end, and a deflectable tip at the distal end of the elongate tubular member, wherein the deflectable tip may comprise a first helical coil having a first diameter and a second helical coil having a second diameter, the first diameter being larger than the second diameter. The first and second helical coils are arranged in the manner of a double helix. When viewed in cross-section, the first helical coil and the second helical coil are aligned at a first point on a circumference of each coil and misaligned at a second point on the circumference of each coil, where the second point is approximately 180 degrees from the first point. In certain cases the first helical coil and the second

helical coil are bonded at one or more points of alignment of the double helix. (Page 3, lines 4-11)

*Corresponding Claims: 1-5, 7-13*

**Species B:** The species describing a catheter comprising an elongate tubular member having a proximal end and a distal end, and a deflectable tip at the distal end of the elongate tubular member, wherein the deflectable tip may comprise a first helical coil having a first diameter and a second helical coil having a second diameter, the first diameter being larger than the second diameter. The first and second helical coils are arranged in the manner of a double helix. When viewed in cross-section, the first helical coil and the second helical coil are aligned at a first point on a circumference of each coil and misaligned at a second point on the circumference of each coil, where the second point is approximately 180 degrees from the first point. In certain cases the first helical coil and the second helical coil are bonded at one or more points of alignment of the double helix. The species further including a dilatation balloon in communication with an inflation lumen. (Page 3, lines 4-10 and 22-24)

*Corresponding Claims: 1-13*

**Species C:** The species wherein the catheter comprises an elongate tubular member having a proximal region, a distal region, and a lumen extending therebetween. A multilayer torque cable is disposed in the proximal region of the elongate tubular member. The multilayer torque cable includes a first helical coil and a second helical coil. The first helical coil is nested within the second helical

coil and wound in a reverse direction from the second helical coil. Rotation of the first helical coil in a first direction causes the first helical coil to expand while rotation of the second helical coil in the first direction causes the second helical coil to compress and thereby interfere with the expansion of the first helical coil. The catheter further includes a monolayer helical coil in the distal region of the elongate tubular member. An outer jacket surrounds the monolayer helical coil to restrict expansion on rotation of the monolayer helical coil. (Page 4, line 20-Page 5, line 3, and Page 5, lines 4-7)

*Corresponding Claim: 23*

**Species D:** The species wherein the catheter comprises an elongate tubular member having a proximal region, a distal region, and a lumen extending therebetween. A multilayer torque cable is disposed in the proximal region of the elongate tubular member. The multilayer torque cable includes a first helical coil and a second helical coil. The first helical coil is nested within the second helical coil and wound in a reverse direction from the second helical coil. Rotation of the first helical coil in a first direction causes the first helical coil to expand while rotation of the second helical coil in the first direction causes the second helical coil to compress and thereby interfere with the expansion of the first helical coil. The catheter further includes a monolayer helical coil in the distal region of the elongate tubular member. An outer jacket surrounds the monolayer helical coil to restrict expansion on rotation of the monolayer helical coil. The catheter further

includes a third helical coil surrounding the second helical coil. (Page 4, line 20-Page 5, line 7)

*Corresponding Claim: 23*

**Species E:** The species wherein the catheter comprises an elongate tubular member having a proximal region, a distal region, and a lumen extending therebetween. A multilayer torque cable is disposed in the proximal region of the elongate tubular member. The multilayer torque cable includes a first helical coil and a second helical coil. The first helical coil is nested within the second helical coil and wound in a reverse direction from the second helical coil. Rotation of the first helical coil in a first direction causes the first helical coil to expand while rotation of the second helical coil in the first direction causes the second helical coil to compress and thereby interfere with the expansion of the first helical coil. The catheter further includes a monolayer helical coil in the distal region of the elongate tubular member. An outer jacket surrounds the monolayer helical coil to restrict expansion on rotation of the monolayer helical coil. The catheter further includes a dilatation balloon. (Page 4, line 20-Page 5, line 7 and Page 6, lines 13-14)

*Corresponding Claim: 23*

**Species F:** The species in which a catheter is provided comprising a proximal handle, a torque cable extending distally from the proximal handle, and an outer jacket extending distally from the proximal handle. The outer jacket surrounds the torque cable with an annular gap disposed between the torque cable and the

outer jacket. The annular gap allows the torque cable to rotate independently of the outer jacket for at least a portion of the length of the catheter. (Page 7, lines 2-6)

*Corresponding Claim: 40*

**Species G:** The species describing the method of providing a catheter having an elongate tubular member with a proximal end and a distal end, and a deflectable tip at the distal end of the catheter, advancing the catheter to a region of interest in an artery proximal a lesion, operating the control wire to direct the deflectable tip toward the lesion, and advancing a guidewire through the lumen of the catheter and into the lesion to cross the lesion. (Page 4, lines 1-5)

*Corresponding Claim: 14*

**Species H:** The species describing a method of providing a catheter comprising an elongate tubular member having a proximal region, a distal region, and a lumen extending therebetween, a multilayer torque cable in the proximal region of the elongate tubular member, a monolayer helical coil in the distal region of the elongate tubular member, and an outer jacket surrounding the monolayer helical coil to restrict expansion on rotation of the monolayer helical coil; advancing the catheter to a region of interest e.g., in an artery proximal to a lesion; and applying torque to the proximal region of the catheter which is transmitted through the multilayer torque cable in the proximal region of the elongate tubular member, and through the monolayer helical coil in the distal

region of the elongate tubular member. (Page 5, lines 15-21 and Page 6, lines 7-10)

*Corresponding Claim: 31*

**Species I:** The species describing a method of providing a catheter comprising a proximal handle, a torque cable extending distally from the proximal handle, and an outer jacket extending distally from the proximal handle and surrounding the torque cable, an annular gap disposed between the torque cable and the outer jacket; and advancing the catheter to a region of interest in the artery proximal a lesion; applying torque to the proximal handle, which is transmitted through the torque cable with the outer jacket remaining stationary for at least a portion of its length. (Page 7, line 18-Page 8, line 1)

*Corresponding Claim: 48*

5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

If electing Group I, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **Species A-F** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5 and 7-13 are considered generic to species A and B, and claim 23 is considered generic to species C, D, and E.

If electing Group II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **Species G-I** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are considered generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victoria P. Campbell whose telephone number is 571-270-5035. The examiner can normally be reached on Monday-Thursday, 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123